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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,669	01/07/2005	Yasuyoshi Ueda	5404/80	2338

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EXAMINER	
MAHYERA, TRISTAN J	
ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,669	UEDA ET AL.	
	Examiner	Art Unit	
	TRISTAN J. MAHYERA	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1-14,17-20,26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-27 are pending. Claims 15 and 16 have been amended. Claims 21-27 have been newly added. Claims 1-14, 17-20, 26 and 27 are withdrawn pursuant to 37 CFR 1.142(b), as being drawn to the non-elected invention. Claims 15, 16 and 21-25 are examined on the merits.

Newly submitted claims 26 and 27 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 26 is directed to oil/fats that have a melting point of not lower than 20C, while claim 27 is directed to oil/fats that have a melting point below 20C. These are distinct oils and fats that do not overlap in function, are independent and distinct from one another and would materially affect the process of producing the enriched food because the oils/fats with a melting point above 20C would be a solid whereas the oils/fats with a melting point below 20C would be a liquid at room or food temperature and would not require melting.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26 and 27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(a-d) is acknowledged.

Claim Rejections - 35 USC § 112 2nd Paragraph

The rejection of Claims 15 and 16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **hereby withdrawn in light of the amendment**.

Claim Rejections - 35 USC § 102

The rejection of Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by SHAPIRA (US 6,156,351 see PTO-892) is **hereby withdrawn in light of the amendments,** specifically that the feed was not enriched with ubiquinol.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15 and 23-25 are **newly** rejected under 35 U.S.C. 102(e) as being anticipated by CHOPRA (US 6,441,050 see PTO-1449).

CHOPRA teaches an oral palatable food composition in liquid form (i.e. beverage) comprising a mixture of ubiquinol and ubiquinone together with a triglyceride (i.e. edible vegetable oil/fat) and a sweetener (i.e. ordinary human food/confection). See e.g. claim 1: instant claims 15 and 24. The triglyceride is present from 0.2 to 50%, which reads on the oil/fat content of not less than 0.5% in claim 23. See e.g. claim 1. The ubiquinol is added to the oil/fat then heated and lastly added to the sweetener. See e.g. col. 9 lines 45-55: instant claims 15 and 25.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 15 and 16 under 35 U.S.C. 103(a) as being unpatentable over SHAPIRA in view of YAJIMA et al. (US 2005/0069996 see PTO-892) is **hereby withdrawn in light of the arguments**. New rejections follow.

Claims 15, 16 and 23-25 are **newly** rejected under 35 U.S.C. 103(a) as being unpatentable over BOROWY-BOROWSKI et al (US 6,045,826, see PTO-892) (BOROWY) in view of BRASCO et al (US 5,258,179 see PTO-1449).

BOROWY teaches a water-soluble composition comprising a lipophilic compound and a solubilizing agent as therapeutics. See e.g. claim 1. The lipophilic compound is an enriched mixture of ubiquinones and ubiquinols. See e.g. claim 2: instant claim 15. The composition is for oral human consumption. See e.g. col. 7 line 59: instant claim 15. The oil/fact containing food are edible oils/fats, e.g. campesterol

and sitosterol. See e.g. claim 3: instant claim 15. The reference further teaches a process of preparing the composition by dissolving or mixing the ubiquinones and ubiquinols, then heating the mixture to a temperature higher than the melting points of the compounds. See e.g. claim 14: instant claim 25.

BOROWY does not teach adding this composition to a food product.

BRASCO teaches foods and therapeutics containing coenzyme Q (ubiquinone) as an antioxidant in foods that contain oils and fats. See e.g. claim 13. The oils and fats can be fish oil or black current seed oil. See e.g. Ex. 1: instant claim 24. The oils in Example 1 are in excess of 0.5%. See e.g. Example 1: instant claim 23.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to a process for producing ubiquinol-enriched oil/fat containing foods comprising adding the ubiquinol and ubiquinone together with an oil/fat containing food to a food material, as taught by BOROWY in view of BRASCO. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single composition because of the beneficial effects of ubiquinone as an antioxidant, as taught by BRASCO. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Regarding claim 16, the purity of ubiquinol is not explicitly mentioned in either reference; however, a purity of greater than 0.01% is a large range that the Examiner believes would cover the ubiquinol used in BOROWY. Furthermore, the large range

claimed demonstrates that a specific purity is not of significance and it is believed that anytime a reference specifically mentions "ubiquinol" the purity will far exceed 0.01%.

Claims 15, 16, 21 and 22 are **newly** rejected under 35 U.S.C. 103(a) as being unpatentable over CHOPRA (US 6,441,050 see PTO-1449).

CHOPRA teaches an oral palatable food composition in liquid form (i.e. beverage) comprising a mixture of ubiquinol and ubiquinone together with a triglyceride (i.e. edible vegetable oil/fat) and a sweetener (i.e. ordinary human food/confection), as taught above.

CHOPRA further teaches that the ubiquinone is converted into ubiquinol by the addition of a reducing agent. See e.g. col. 10 lines 14-20. The ratio of ubiquinol/ubiquinone (instant claim 21) is not explicitly mentioned, nor is the percent of the composition as ubiquinone (instant claim 22), however, given that the ubiquinone is converted to ubiquinol, it is the Examiners belief that the ubiquinone will be less than 50% by weight after conversion, and specifically between the range of 0.0001 to 50%. Instant claims 21 and 22.

Regarding claim 16, the purity of ubiquinol is not explicitly mentioned in the reference; however, a purity of greater than 0.01% is a large range that the Examiner believes would cover the ubiquinol used in CHOPRA. Furthermore, the large range claimed demonstrates that a specific purity is not of significance and it is believed that

anytime a reference specifically mentions "ubiquinol" the purity will far exceed 0.01%, especially after conversion of ubiquinone to ubiquinol.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make a process for producing ubiquinol-enriched oil/fat containing foods comprising adding the ubiquinol and ubiquinone together with an oil/fat containing food to a sweetener/food material at elevated temperature, as taught by CHOPRA. There is motivation to have ubiquinone in a lower ratio or proportion because CHOPRA teaches converting a portion of ubiquinone to ubiquinol. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Response to Amendments and Arguments

Applicants' amendments are sufficient to render the rejection under SHAPIRA moot. Applicants' argument regarding the 103 rejection is found persuasive and new rejections follow.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is

571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615